

## II. Remarks

Claims 2-5, 7, 8, and 10-23 are pending in this application, with claim 2 having previously been deemed generic, and with claims 4 and 5 having been provisionally withdrawn as directed to a non-elected species.

In the final Office action, the examiner has asserted a construction of the "means plus function" elements of claims 2, 7, 8, 11, and 20 that denies Applicants' affirmative invocation of Section 112, paragraph 6. And, based upon that claim construction, claim 12 stands finally rejected for lack of written description; claims 2, 3, 7, 8, 13, and 17-19 stand finally rejected as anticipated by either CA 2,432,623 ("Kawaguchi '623") or its counterpart U.S. pre-grant publication US 2004/0104246 A1 ("Kawaguchi '246"); and claims 1, 11, 14-16, and 20-23 stand finally rejected for obviousness over Kawaguchi '623 in view of at least one other prior art reference. Finally, claims 20 and 21 stand objected to for reciting an improper dependency and a clerical error, respectively.

By this paper, Applicants have now cancelled, without prejudice to further prosecution, provisionally-withdrawn claims 4 and 5. Applicants have also amended claims 2, 7, and 20 to more particularly point out and distinctly claim that which they regard as their invention. In particular, Applicants have sought to improve the syntax and structure of independent claims 2 and 7 while further separating certain means-plus-function elements from the other structural elements with which they were previously combined, while new claims 24-28 recite some of these previously-recited structural elements of their respective base claims 2 and 7. Dependent claims 3, 8, 10, 11, and 12 have also been amended to improve claim syntax or to otherwise be consistent with the amendments to claims 2 and 7. Finally, Applicants have amended claims 20 and 21 to correct the informalities identified by the Examiner. Applicants respectfully submit that no new matter has been added by virtue of these amendments.

Reconsideration and further examination of claims 2, 3, 7, 8, and 10-23, and consideration and examination of new claims 24-29, are respectfully requested.

## APPLICANTS HAVE INVOKED TREATMENT UNDER 35 U.S.C. §112, ¶6

Applicants respectfully submit that claims 2, 7, 8, 11, and 20 as amended properly invoke “means-plus-function” treatment under 35 U.S.C. §112, sixth paragraph. Specifically, as the Court of Appeals for the Federal Circuit emphasized in Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1368-69 (Fed. Cir. 2005), “the word ‘means’ in the claim element raises the presumption that §112, ¶6 applies,” and if “the claim element includes a well delineated function ... without any recited structure for performing the function,” then the claim element is properly accorded treatment under Section 112, sixth paragraph.

Independent claims 2, 7, and 20 as currently amended, continue to recite one or more elements in “means-plus-function” form, with a “well-delineated function” and “without any recited structure for performing the function,” to thereby properly invoke treatment under 35 U.S.C. §112, sixth paragraph. For example, claims 2 and 20 now identically recite a “first means for threadably attaching the rigid tube part to the laminated paper packaging system, whereby the connector is screwed to the laminated paper packaging system, the first means further defining a second part of the passageway when threadably attached to the laminated paper packaging system,” while claim 2 further recites a “second means for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system.” Each of these means-plus-function elements are properly accorded §112, ¶6 treatment in accordance with Callicrate, as each recites a “well-delineated function ... without any recited structure for performing the function” (Applicants submit that the functional recitation “threadably attaching” does not itself recite the specific structure by which the function is performed, or how the second part of the passageway is defined, without resorting to the specification for the corresponding structure; while the recited “second means for opening ... upon screwing” of claim 2 is itself similar to the “cutting means” limitation construed in Callicrate as properly invoking §112, ¶6 treatment).

Applicants note that the structure generally corresponding to the “second means for opening” is described, for example, at page 3, line 18 through page 4, line 3, either as a “cutting member protruding from the connector device” that is

"intended to cut the laminated paper packaging system upon screwing the connector device onto the frame-like member of the laminated paper packaging system" (emphasis added); or the combination of a "triggering member" on the connector device that "acts upon a leverage system" on the packaging system's frame-like member, which in turn operates to cut the surface of the packaging system. By its own terms, claim 2 is limited to the first species of the disclosed "means for opening" (wherein "opening" occurs "upon" screwing" the connector device onto the packaging system). And, as explicitly described at specification page 12, lines 1-3:

The length, position and number of cutting means 13, e.g., projecting means, may be adapted to cut laminated paper packaging system 4 when connector device is connected, e.g. sealably connected, thereto, e.g. screwed onto frame-like member 11.

(Emphasis added.) Thus, properly construed in view of the disclosure under the mandate of 35 U.S.C. §112, sixth paragraph, the recited "means for opening ... upon screwing" means a cutting member that begins to cut the surface of the packaging system only after the mating threaded portions of the recited "means adapted to fit..." have begun to threadably engage each other (as one can only "screw" together threaded components that have at least initially engaged one another).

Applicants further note that this construction is fully consistent other claims (for example, original claim 3 which further recites "cutting ... upon screwing"), and with the stated objective of preserving the sterility of the composition within the laminated paper packaging system (see, e.g., specification page 4, lines 4-23).

Regarding independent claim 7 as amended by this paper, claim 7 now recites "attachment means for fixedly attaching the connector device to the first surface of the laminated paper packaging system upon penetration of the first spike and pressing of the connector device against the first surface of the laminated paper packaging system" (emphasis added). The disclosed structure corresponding to the recited "attachment means for fixedly attaching ... upon penetration ... and pressing of the connector device against the first surface" is either a rim or flange 50 on the connector device 1, facing toward the first surface of the laminated paper packaging system, on which an adhesive layer 19 has been provided, whereupon the adhesive

layer 19 fixedly attaches the connector device 1 to the laminated paper packaging system 4 (see, e.g., specification page 16, lines 11-19, and Figure 4); or two axially-spaced rims 50,51 on the spike trap the punctured surface of the laminated paper packaging system 4, the rim 51 closer to the spike's point being made of a flexible material and the rim 50 farther from the spike's point being made of a rigid material (see, e.g., specification page 16, line 21 to page 17, line 1).

Finally, dependent claim 10 as amended recites a "first venting means for venting an interior of the laminated paper packaging system subsequent to penetration of the spike," without further describing the structure (such as the disclosed one-way valve) by which the function is achieved.

## THE CLAIMS REJECTIONS

Turning to the substantive rejections presented in the final Office action, claims 2, 3, 7, 8, 13, and 17-19 stand rejected under 35 U.S.C. §§102(b) and 102(e) as being anticipated by Kawaguchi '623 and its U.S. counterpart, pre-grant publication Kawaguchi '246 (collectively referred to hereinafter as "Kawaguchi," with citations made only to the pre-grant published application for clarity). Applicants respectfully traverse the rejections with respect to claims 2, 3, 7, 8, 13, and 17-19.

Kawaguchi teaches an adapter for a beverage pack in which an elastic "fixing member" having a through-hole is first secured to the beverage pack such that the through-hole "is aligned with the opening in the beverage pack" (para. 0010), whereupon the pointed "distal end" of a generally tubular adapter 12 is inserted into the beverage pack through the through-hole and the opening, whereupon the elastic fixing member elastically deforms about the adapter to achieve a seal about the adapter (para. 0010).

Kawaguchi teaches several variations of the adapter, some of which include peripheral features which engage the flexible fixing member over its nominal thickness to achieve an improved seal and prevent unintended pull-out, such as a locking ridge SR as seen in Figure 2, and peripheral threads SS as seen in Figure 4. In each embodiment, though, the adapter body is said to be "formed by injection molding from a semi-hard material such as polypropylene, polyethylene, or another

polyolefin, or polycarbonate, polystyrene, or the like" (para. 0029). A further variation, shown in Figure 6, includes a flexible, tubular "linking member 114" having a wide radial flange on one end that is secured by an adhesive to the top of the beverage pack, and a narrow radial flange on the other end that cooperates with a rigid, encompassing "annular member" or collar 112b on the adapter body 112 to thereby lock the adapter 110 within the linking member 114.

Significantly, Kawaguchi emphasizes that, when attaching the adapter 10, "the pointed end 12a punctures the film 21 [on the beverage pack 20] and goes into the opening 21, but the flange 12c serves as a stopper so that only the pointed end 12a enters the beverage pack 20" (para. 0040) – in other words, the pointed end has punctured the film on the beverage pack well in advance of the engagement of any flange 12c or other peripheral sealing feature, such as the sealing ridge SR or male threads SS, with the fixing member 14 atop the beverage pack.

Thus, Kawaguchi teaches only flexible elements secured to the top of the beverage package (the elastic "fixing member 14" shown in Figures 1-5, and the elastic "linking member 114" of Figure 6), and only teaches the use of threads to improve the "elastic fit" achieved between the adapter body and the relatively-thin elastic "fixing member 14." Simply stated, Kawaguchi fails to teach a connector device that includes "first means for threadably attaching the rigid tube part to the laminated paper packaging system, whereby the connector is screwed to the laminated paper packaging system, the first means further defining a second part of the passageway when threadably attached to the laminated paper packaging system," and second means for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system" (emphasis added).

And, because Kawaguchi teaches gluing its elastic fixing member or elastic linking member to the top of the beverage pack before elastically capturing the adapter body within the fixing member's through-hole or the linking member's axial bore, Kawaguchi likewise fails to teach a connector having a rim or flange, facing toward the packaging system, on which an adhesive layer has been provided for fixedly attaching the connector device to the packaging system, as recited in

independent claim 7. Still further, because Kawaguchi employs a "semi-hard material" for its adapter body when relying upon the elastic fixing member adhered to the top of the beverage pack to cooperatively achieve a seal, Kawaguchi not only fails to teach a pair of axially-spaced rims or flanges as recited in dependent claim 8, wherein the one located nearer the point of the spike is made from a flexible material and the one located farther from the point of the spike is made from a rigid material, but Kawaguchi must necessarily be viewed as teaching away from such a construction.

For at least the foregoing reasons, Applicants respectfully submit that independent claims 2 and 7, as well as dependent claims 8, 13, 17, and 18, are neither anticipated by, nor obvious in view of, Kawaguchi.

Claims 14 and 16 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi in view of Quinn and U.S. Patent No. 5,993,422 ("Schafer"), while claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi in view of Quinn and U.S. Patent No. 3,001,525 ("Hendricks").

Once again, while the Examiner is correct in identifying Quinn as using a laminated paper packaging system for enteral administration, Schafer as disclosing use of a pump, and Hendricks as teaching parenteral equipment that includes an intermediate bag for mixing solutions, Quinn, Schafer, and Hendricks, taken either singly or in combination, do not cure the deficiencies of Kawaguchi as described above with respect to independent claim 2, from which claims 14-16 each indirectly depends. Accordingly, for at least those reasons, Applicants respectfully submit that claims 14-16 are patentable over the art of record in this application.

Claims 10 and 11 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi '623 in view of U.S. Patent No. 4,997,429 ("Dickerhoff"). Applicants respectfully traverse.

While the Examiner is correct in identifying Dickerhoff as teaching an enteral bottle cap having a vent valve 38 that permits entry of air into the container from which fluid is being drawn, Dickerhoff does nothing to cure the deficiencies of

Kawaguchi as described above with respect to independent claim 2, from which claims 10 and 11 each directly depend. Accordingly, for at least those reasons, Applicants respectfully submit that claims 10 and 11 are patentable over the applied combination of Kawaguchi '623 and art of record in this application.

Finally, claims 20-23 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi in view of U.S. Patent No. 6,485,479 ("Knierbein"). Applicants respectively traverse.

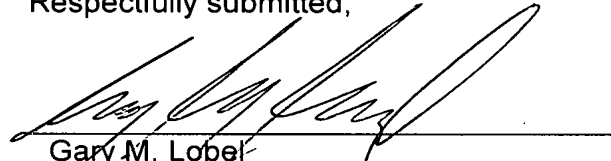
Applicants respectfully submit that Kawaguchi and Knierbein are divergent teachings. Specifically, as noted above, Kawaguchi teaches an adapter for a beverage pack in which an elastic "fixing member" having a through-hole is first secured to the beverage pack such that the through-hole "is aligned with the opening in the beverage pack" (para. 0010), whereupon the pointed "distal end" of a generally tubular adapter 12 is inserted into the beverage pack through the through-hole and the opening, whereupon the elastic fixing member elastically deforms about the adapter to achieve a seal about the adapter (para. 0010).

Knierbein, on the other hand, teaches a rigid sterile connector whose lower "coupler 2 with a bottom 3 shaped like a boat" and with "wing-like shoulders 7,8 carry[ing] ribs 9 that taper to a point on the ends of the shoulders 7,8" are welded "to the inside of the bag film of suitable film bags for medicinal liquids" (col. 2, l. 67 to col. 3, l. 8; and col. 4, ll. 54-59). The lower portion of a "channel-like passage 17" defined within the Knierbein connector 1 "is covered and sealed with a puncturable membrane film 18" (col. 3, ll. 58-60), which thus itself forms a portion of the film bag. Upon removal of an integrally-formed "protective cap 5," an assembly that includes a "plunge pin or spike 19" and a "sleeve nut 20" is screwed onto the upper portion of the Knierbein connector 1, whereupon the plunge pin or spike 19 "punctures" the membrane film 18 (col. 4, ll. 21-23 and 36-38) to thereby extend into the interior of the film bag, while a "continuous edge 23 beneath" the "upper shoulder 22 of the plunge pin 19" is shown and described as being "thus clamed between the tubular top 4 and an inwardly protruding edge 25 of the sleeve nut 20" (as seen in Figures 4 and 5, and described at col. 4, ll. 30-44) to thereby seal the plunge pin or spike 19 to the coupler 2.

Simply stated, instead of first securing an elastic fixing member to a surface of an otherwise complete beverage pack and thereafter mechanically capturing a penetrating spike through elastic radial deformation of the "fixing member" as taught by Kawaguchi, Knierbein divergently teaches integrating a rigid coupler 2 within a film bag itself (such that the coupler's puncturable membrane film 18 itself defines part of the film bag containing the medicinal liquid), and then uses a sleeve nut 20 to thereafter secure a plunge pin or spike 19 within the coupler's channel-like passage 17, without any elastic radial deformation of any portion of the coupler 2. As such, Applicants respectfully submit that there is no teaching, suggestion, or motivation to combine the Kawaguchi and Knierbein references in the manner suggested by the Examiner and, hence, the withdrawal of the obviousness rejection of claims 20-22 is respectfully requested.

From the foregoing, Applicants respectfully submit that claims 2, 3, 7, 8, and 10-29 are patentable over the prior art of record in this application, and a notice of allowability with respect to claims 2-5, 7, 8, and 10-29 is courteously solicited.

Respectfully submitted,



Gary M. Lobel  
Attorney for Applicants  
Reg. No. 51,155

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7954

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